

DETAILED ACTION

1. This application is a RCE of SN 10/509,952.
Claims 1-7 are pending.

2. ***Examiner's Amendment***

Authorization for this examiner's amendment was given in a telephone interview with Joseph F. Murphy on June 17, 2010.

Claims 1, line 6, after the term ethanol, insert –and--;

line 7, delete the term "tert-butyl alcohol and n-butyl alcohol";

line 8-9, after the term "chloroform" insert –and--;
after the term "methylene dichloride", delete the terms
"carbontetrachloride and ethylene dichloride.

3. ***Reason for Allowance***

The following is an examiner's statement of reasons for allowance:

By the above examiner's amendment, applicants have limited the scope of the claims to using the solvent system of mixtures of methanol/ethanol/isopropanol and chloroform/methylene dichloride. Two newly available documents provided support that solubility of donepezil hydrochloride is highly empirical (see Aricept drug description) and the solubility of compound in a known mixture of solvents can be extrapolated to other mixtures of similar Hansen solubility constants (see Solvents Wikipedia). Therefore, the 112 first paragraph rejection is obviated in view of the amendment limiting to those solvents with similar δD i.e. methanol/ethanol/isopropanol mixed with chloroform/methylene dichloride guided by the examples operable with the Hansen solubility table. The rejection of 102(e) is dropped in view of the δD of mixtures described by the specification which would not be anticipated by trace amount. The 103(a) rejection is obviated because the above two references provided conventional skill in operating mixture of solvents for which the prior art solvent system by Sugimoto

'841 since one would not pick and choose solvents that the compound is insoluble or mixture that has diversified δD values. Claims 1-7 as currently amended are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

- Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
June 17, 2010

/Celia Chang/
Primary Examiner
Art Unit 1625